

**REMARKS**

Claims 1-16 were previously canceled.

Claims 17-25 are amended to recite “isolated” strain.

Claims 17-19 are amended to refer to an isolated strain of *Saccharomyces cerevisiae* I-2971, I-3142 and I-3143, respectively, as suggested by the Examiner.

Claims 20 is amended to refer to an isolated strain of *Saccharomyces cerevisiae* and by incorporating subject matter from claim 21. Claim 20 is further amended to improve its form.

Claim 21 is amended in accordance with the amendment to claim 20.

Claims 22 is amended to additionally refer to claims 18, 19 or new claims 28 or 40.

Claims 23-34 are amended to improve their form.

Claims 38-41 are added as new claims. Support is found, for example at page 4, the 2<sup>nd</sup> and 3<sup>rd</sup> full paragraphs of the specification as filed.

No new matter is presented.

**I. Response to Claim Objections**

Claims 17-19 are objected to for the name of the depository and the deposition dates.

Claims 17-19 are amended as set forth above as suggested by the Examiner, thereby obviating the objection.

Claims 24-25, 28 and 34 are objected to for “characterized in that”.

Claims 24-25, 28 and 34 are amended by replacing the phrase “characterized in that” with “wherein”, as suggested by the Examiner, thereby obviating the objection.

Accordingly, Applicants respectfully request withdrawal of the objections to the claims.

## **II. Use Claims**

Claims 29 and 35 are rejected under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e. results in a claim which is not a proper process claim under 35 U.S.C. § 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 29 and 35 are amended to recite positive steps of mixing dough ingredients and adding the specified baker's yeast, thereby obviating the rejection.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 101.

## **III. Response to Claim Rejections under 35 U.S.C. § 112, 1<sup>st</sup> Paragraph**

Claims 20-22 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

Without conceding the merits of the rejection, claim 20 is amended by incorporating subject matter of claim 21 to recite that the specified *Saccharomyces cerevisiae* in strain, in test PT<sub>2</sub>, gives a decrease in the proof time relative to the reference strain NCYC 996 which is equal to at least 80% of the decrease in proof time obtained in test PT2 with strain I-2917 according to claim 17 relative to said reference strain NCYC 996.

In making a determination of enablement, the proper inquiry is whether one of ordinary skill in the art would be able to use the claimed invention *without undue experimentation*. There are several factors which must be weighed and considered to determine whether any necessary experimentation can be considered as undue: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill in the art; (5) the

level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make and use the invention based upon the disclosure. See MPEP § 2164.01(a).

Indeed, the skilled artisan knows how to derive new strains from initial strain I-2971 by conventional hybridization or mutation techniques. Then the skilled artisan can test obtained new strains to check whether they substantially share the same properties as initial strain I-2971 or not, in terms of tolerance to sugar. Such is considered to be routine experimentation, rather than undue experimentation. In this respect, amended claim 20 provides a criterion based on the test PT<sub>2</sub> which is provided in the specification. In other words, contrary to the Examiner's assertion, it is set forth whether the resultant species would have the same properties.

In summary, the skilled artisan would be able to produce strains according to claim 20 based on basic hybridization and mutation techniques. Further, one of ordinary skill in the art would be able to practice the claimed invention without doubt as to which strains are encompassed by claim 20 and which strains are not, since claim 20 provides a quantitative criterion for distinguishing between the encompassed and non-encompassed strains.

Accordingly, Applicants respectfully request withdrawal of the §112, 1<sup>st</sup> paragraph rejection.

Claims 17-19 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

Applicants respectfully submit that the yeast strains required to practice the claimed invention have been deposited according to the Budapest Treaty. A Statement of Availability for each yeast strain is submitted herewith indicating that each of the required yeast strains will be

irrevocably and without restriction released to the public upon issuance of a patent in order to satisfy the deposit requirement.

Accordingly, Applicants respectfully request withdrawal of the §112, 1<sup>st</sup> paragraph rejection.

**IV. Response to Claim Rejections under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph**

Claims 20-37 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

Claim 20 is rejected allegedly because there is insufficient antecedent basis for the term "by one or more hybridizations or by mutation of a strain".

Claim 20 is amended by replacing the expression "*by one or more hybridizations or by mutation of a strain*" with the expression "*by hybridizing or by mutating a strain*", thereby obviating the rejection.

Claims 27 and 33 are rejected allegedly because there is insufficient antecedent basis for the phrase "*the fermentation*".

Applicants traverse the rejection and submit that the article "*the*" is not present before "*fermentation*" in claims 27 and 33. Thus, Applicants submit that the rejection is improper.

Claim 21 is rejected allegedly because the expressions "*proof time*" and "*PT<sub>2</sub>*," are unclear.

Applicants traverse the rejection and submit that the term "proof time" is a term of art commonly used in the bread-making industry. Further, this term is defined in the specification at page 5, the 1<sup>st</sup> paragraph of the specification. Moreover, the complete definition of the PT<sub>2</sub> test and of the way the proof time is measured in this test is in fact recited in the specification at

pages 11-13 of the specification. Therefore, there is absolutely no ambiguity as to the meaning and scope of claim 21, when properly read in the light of the specification.

Claims 21, 25, 27-28 and 33-34 are rejected as reciting both broad and narrow range limitations.

The claims are amended herein, thereby obviating the rejection.

Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph.

**V. Response to Claim Rejections under 35 U.S.C. § 101**

Claims 17-25 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Claims 17-25 read upon naturally-occurring strains. The claims do not recite the term “isolated strain”.

The claims are amended to recite an “isolated strain”, thereby obviating the rejection.

Accordingly, Applicants respectfully request withdrawal of the rejection.

**VI. Response to Claim Rejections under 35 U.S.C. § 102**

Claims 17-19 are rejected under 35 U.S.C. § 102(a).

According to the Examiner, the Applicants admit that the strains were deposited in 2003 and there is no way for the Patent Office to know which inventor or inventors contributed to which strains, or if they all did.

Applicants traverse the rejection as improper.

Upon the filing of the application, an executed Declaration signed by all inventors, was submitted referencing the specification of the present application and indicating that all inventors contributed the claimed invention. Thus, the signed Declaration is sufficient evidence that all inventors contributed to the claimed invention. On the other hand, the Examiner has not

presented a reasonable basis for doubting the executed Declaration. Accordingly the rejection is improper and should be withdrawn,

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(a).

**VII. Response to Claim Rejections under 35 U.S.C. § 103**

Claims 17-37 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Satoshi et al. (1994, construction from a single parent of Baker's yeast strains with high freeze tolerance and fermentative activity in both lean and sweet doughs; hereinafter R1) in view of Hill (U.S. 4,318,991; hereinafter R2).

Applicants respectfully traverse the rejection for the following reasons.

The claims of the present application are directed to three specific yeast strains (1-2971, 1-3142 and 1-3143), to strains derived from these three specific yeast strains, to products containing or based on said strains, and to methods using said strains or products.

The strains which are the crux of the present invention have a very high tolerance to sugar, in the presence or not of mold inhibitors (see page 4, the 2<sup>nd</sup> full paragraph).

The Examiner states that R1 teaches a hybridization process for generating yeast strains which are highly resistant to a high sugar content in bread dough; that R2 teaches how to make a yeast strain tolerant to organic acids; and that it would have been obvious to combine the teachings of R1 and R2 so as to produce strains having both a high sugar tolerance and preservative tolerance. There would thus be a reasonable expectation of success in developing the claimed *Saccharomyces cerevisiae* strains.

Contrary to the Examiner's statements:

- there would be no reasonable expectation of success in developing the

very *Saccharomyces cerevisiae* strains which are claimed, because the method used in R1 and R2 for producing yeast strains is very different from the method used in the present application for producing the claimed strains;

- there would be no reasonable expectation of success either in developing other *Saccharomyces cerevisiae* strains which would have the same properties as the claimed strains, because R1 and R2 do not teach how to obtain strains with as high a tolerance to sugar as the presently claimed strains; there is no suggestion either in R1 and R2 as to how to obtain strains having a higher tolerance to sugar than those of R1 and R, and, thus as to how to arrive at the presently claimed strains.

**The combined teachings of R1 and R2 would not lead to the claimed strains *per se***

In R1, all strains are obtained by hybridization techniques starting from one single parent, namely strain TYR (see the title, the abstract and the 1<sup>st</sup> paragraph of the Discussion section of R1). The specificity of strain TYR is its freeze-tolerance (see the first paragraph of the Materials & Methods section of R1). Its level of tolerance to sugar is not known.

On the other hand, R2 teaches how to propagate yeast in the presence of organic acids but does not disclose any method of producing new yeast strains.

In contrast, the claimed strains were obtained by cross-hybridizing commercial strains (used in the bread-making industry) or strains from public collection centers known to have osmotolerance property and/or low sensitivity to mold inhibitors (see page 4, the 2<sup>nd</sup> full paragraph).

In R1, the genetic material of the obtained strains is substantially the same as that of the single initial strain TYR, although rearranged in a random manner, whereas the strains obtained according to the present invention have a genetic material which is the result of random combinations of various genetic materials from various initial strains.

Consequently, even if one of ordinary skill in the art were to combine the teachings of R1 and R2 and generate yeast strains based on the combined teachings, the claimed strains would not be obtained. Instead more variants derived from the TYR strain would be obtained. That is strains having a genetic material substantially different from that of the TYR strain, such as for example the strains of the claimed invention, would not be obtained.

Applicants also wish to emphasize that the production of all strains from a single parent strain (rather than from multiple strains) is an essential feature of R1. See the first paragraph of the Discussion section in this respect. Therefore, the skilled person would not have departed from this technique and would not have used the same path as the present invention for obtaining new strains.

Thus, the combined teachings of R1 and R2 would not lead to strains having similar properties to those of the claimed invention.

Despite the Examiner's statement that R1 teaches how to obtain strains with a high tolerance to sugar, R1 does in fact not disclose such strains.

Indeed, the initial parent strain from which all final strains are obtained is a freeze-tolerant strain, but not necessarily a sugar-tolerant strain. The selection of clones is then performed by assessing their respective leavening activity in lean dough, and not on sweet dough. See the first paragraph of the Discussion section in this respect. In other words,



performance of the yeast in the presence of a high level of sugar is not used as a criterion in the selection process in R1.

Performance on sweet dough is only assessed for the strains finally retained in order to classify them into four groups (see the Results section in R1).

Therefore, the teaching of R1 is not directed to the production of strains having an improved efficiency in the presence of sugar, contrary to the present invention, where the strains are selected according to a bread-making test in the presence of sugar and mould inhibitors.

A comparison of the results presented in R1 with those of the present application confirms that the strains obtained in R1 do not perform as well as those of the present invention at a high level of sugar. Indeed, it can be seen from Table 4 in R1, the CO<sub>2</sub> production of eleven hybrid strains in sweet dough (containing 30% sugar) is compared with that of the parent strain TYR and with that of three control strains. Among these three reference strains, KY5649 is a commercial strain which is recommended for regular and sweet dough (see the first paragraph of the Materials & Methods section).

It turns out that out of the eleven hybrid strains presented in the Table 4 of R1, only five produce more CO<sub>2</sub> than the initial TYR strain, and that only four produce more CO<sub>2</sub> than the control KY5649 strain. If we now look at strain No. 893, which produces the highest amount of CO<sub>2</sub> in sweet dough, this strain produces approximately 4% more CO<sub>2</sub> than the control KY5649 strain.

In the present application, the performance of the strains according to the invention is assessed in a dough containing even more sugar (namely 40% sugar in the PT<sub>2</sub> test, see Table 1). The efficiency of the strains is monitored by measuring the proof time. Said proof time is decreased by 25 % to 35 % owing to the strains according to the invention, relative to the control

strain NCYC 996 (see Table 2). Strain NCYC 996 is the reference strain for commercial baker's yeasts effective on sweet dough, as explained in paragraph 24 of the present application.

Of course, the results of R1 may not be directly compared with those of the present application because the test conditions are not the same. In particular, the assessment of the proof time (like in the present application) is much more relevant for the purposes of implementation for bread-making at the industrial level than the measurement of the amount of CO<sub>2</sub> produced (like in R1). Nevertheless, from the data it can be reasonably be inferred that the strains according to the present invention appear to be more efficient than those of R1 at a high concentration of sugar, since they result in a very significant decrease in the proof time in the presence of 40% of sugar relative to the reference strain, whereas the best strain in R1 only yields a 4% increase in the amount of CO<sub>2</sub> produced in the presence of 30% sugar.

The shortcomings of R1 in this respect are not remedied by the teachings of R2, since R2 is silent as to the production and selection of new strains and is also silent as to the issue of performance in the presence of sugar.

In view of the above, the claimed invention is not taught or suggested by the cited references, whether taken alone or in combination. The skilled person starting from R1 would neither obtain the claimed yeast strains, nor other yeast strains having similar properties in terms of tolerance to sugar (in the presence or not of mold inhibitors), even assuming that R2 was relied on as a secondary reference.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103.

**VIII. Conclusion**

In view of the foregoing, the Applicant believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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**23373**

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